

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA, *ex rel.*  
CHINYELU DUXBURY,

Relator,

v.

ORTHO BIOTECH PRODUCTS, L.P.,

Defendant.

Civil No. 03-12189 (RWZ)

The Honorable Rya W. Zobel

**DEFENDANT'S ANSWER TO FIRST  
AMENDED COMPLAINT**

**DEMAND FOR JURY TRIAL**

Defendant Ortho Biotech Products, L.P., (hereinafter "Defendant"), in answer to Relator Chinyelu Duxbury's First Amended Complaint ("First Amended Complaint"), states as follows:

**AS TO SUMMARY OF CLAIM**

1. Paragraph 1 contains Relator's characterization of her claims, to which no answer is required. To the extent an answer is required, Defendant denies that this action consists of three counts to recover damages and civil penalties on behalf of the United States of America under the Federal Civil False Claims Act ("FCA"). Rather, the First Amended Complaint has been limited as follows. First, on June 27, 2007, the parties jointly stipulated to the dismissal of Count II (the "AWP Claim"). Second, on August 12, 2009, the U.S. Court of Appeals for the First Circuit affirmed this Court's January 28, 2008, decision dismissing all counts alleged by Dean McClellan and Count III (the "Off-Label Claim") alleged by Relator in the First Amended Complaint. Finally, this Court's September 27, 2010, decision further narrowed the scope of Relator's Count I (the "Kickback Claim") to (i) the eight-month period from November 6, 1997 to July 20, 1998 and (ii) only a very few provider accounts: St. Josephs Hospital, Tacoma, Washington; Rainier Oncology of Puyallup, Washington; Western Washington Cancer Treatment Center in Olympia, Washington; Memorial Clinic in Olympia, Washington; and

Memorial Clinical Oncology Group in Washington. Defendant is not required to respond in this Answer to any claims and allegations in the First Amended Complaint that go beyond the scope of the Court's September 27, 2010, Order, and Defendant's non-response to any such allegations is not intended to and shall not constitute any admissions by Defendant. To the contrary, all such allegations in the First Amended Complaint are denied. Defendant denies that Relator is entitled to any relief and denies the remaining allegations of Paragraph 1.

2. Defendant admits that Procrit is the brand name for epoetin alfa and that Procrit has been approved by the FDA for use in treating anemia, among other conditions. Defendant denies the remaining allegations of Paragraph 2. Defendant is without sufficient information to admit or deny the remaining allegations of Paragraph 2; those allegations are therefore denied.

3. Paragraph 3 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies the allegations of Paragraph 3.

4. Paragraph 4 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies the allegations of Paragraph 4.

5. Paragraph 5 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies the allegations of Paragraph 5.

6. The allegations of Paragraph 6 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required.

7. The allegations of Paragraph 7 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required.

8. Paragraph 8 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies the allegations of Paragraph 8.

**AS TO PARTIES**

9. Defendant admits that Mark Eugene Duxbury was employed by Defendant for a period of time before he was fired in 1998 for making racially and sexually harassing remarks and for failing to complete his expense reports timely and accurately. Defendant further denies that Mr. Duxbury is still the Relator in this case. Mr Duxbury passed away on October 13, 2009, and the administrator of his estate, Chinyelu Duxbury, has been substituted as the Relator. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to and shall not respond to any allegations in the First Amended Complaint relating solely to him. Defendant is without sufficient information to admit or deny the remaining allegations of Paragraph 9; those allegations are therefore denied.

10. Defendant admits that it was a New Jersey limited partnership doing business in Massachusetts when the First Amended Complaint was filed.

**AS TO JURISDICTION AND VENUE**

11. Paragraph 11 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

12. Paragraph 12 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

13. Paragraph 13 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

14. Paragraph 14 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

15. Paragraph 15 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

**AS TO ORIGINAL SOURCE ALLEGATIONS**

16. Paragraph 16 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

17. Defendant admits that Mark Eugene Duxbury was employed by Defendant for a period of time before he was fired in 1998 for making racially and sexually harassing remarks and for failing to complete his expense reports timely and accurately. Defendant further denies that Mr. Duxbury is still the Relator in this case. Mr Duxbury passed away on October 13, 2009, and the administrator of his estate, Chinyelu Duxbury, has been substituted as the Relator. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating solely to him. Defendant is without sufficient information to admit or deny the remaining allegations of Paragraph 17; those allegations are therefore denied.

18. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating solely to him. Defendant is without sufficient information to admit or deny the remaining allegations of Paragraph 18 relating to Mr. Duxbury; those allegations are therefore denied.

19. The allegations of Paragraph 19 relate solely to Count II of the First Amended Complaint. Because the parties jointly stipulated to the dismissal of Count II (the “AWP Claim”) of the First Amended Complaint on June 27, 2007, no response to these allegations is required. To the extent that a response is required, the allegations of this paragraph are denied.

20. Defendant is without sufficient information to admit or deny the allegations of the first sentence of Paragraph 20; those allegations are therefore denied. The second sentence of paragraph 20 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this sentence are denied.

21. The allegations of Paragraph 21 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required.

22. Paragraph 22 sets forth legal conclusions, which do not require a response. Moreover, because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating to him. To the extent that a response is required to this paragraph, the allegations are denied.

23. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating to him. Defendant is otherwise without sufficient information to admit or deny the allegations of Paragraph 23; the allegations are therefore denied.

24. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating to him. Defendant is without sufficient information to admit or deny the allegations of Paragraph 24 relating to Mr. Duxbury's personal knowledge; those allegations are therefore denied. Defendant denies all remaining allegations in Paragraph 24.

25. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating to him. Defendant is without sufficient information to admit or deny the allegations of Paragraph 25

relating to Mr. Duxbury's personal knowledge; those allegations are therefore denied. Defendant denies all remaining allegations in Paragraph 25.

26. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating to him. Defendant is without sufficient information to admit or deny the allegations of Paragraph 26 relating to what documents Mr. Duxbury has or what they show; those allegations are therefore denied. Defendant denies all remaining allegations in Paragraph 26.

27. Because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating to him. Defendant is without sufficient information to admit or deny the allegations of Paragraph 27 relating to Mr. Duxbury's personal knowledge; those allegations are therefore denied. In addition, the final item (5) in the series set forth in Paragraph 27 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations are denied. Defendant denies all remaining allegations in Paragraph 27.

28. Paragraph 28 sets forth legal conclusions, which do not require a response. In addition, because all counts alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to allegations relating solely to him. To the extent that a response to this paragraph is required, the allegations of this paragraph are denied.

**AS TO FIRST-TO-FILE ALLEGATIONS**

29. Paragraph 29 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied except as previously found by this Court.

30. Paragraph 30 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied except as previously found by this Court.

31. Paragraph 31 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied except as previously found by this Court.

### **AS TO FACTUAL BACKGROUND**

Responding to the paragraphs listed as subheadings “A.” and “1.” in the Factual Background section, Defendant states that those paragraphs set forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies that the subsequent paragraphs recite any or all relevant legal provisions and denies the allegations of the paragraphs listed as subheadings “A.” and “1.” to the extent they are inconsistent with applicable rules, regulations and other laws.

32. Paragraph 32 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with the FCA and its legislative history. Defendant also states that the FCA speaks for itself.

33. Paragraph 33 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with the responsibilities of the Department of Health & Human Services (“HHS”), Centers for Medicare and Medicaid Services (“CMMS”), and the Health Care Financing Administrations (“HCFA”).

34. Paragraph 34 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with rules, regulations and other laws that apply to coverage under the Medicare Program.

35. Paragraph 35 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with the FDCA, relevant FDA regulations, and other applicable law.

36. Paragraph 36 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with the rules, regulations and other laws that apply to coverage under the Medicare Program.

37. Defendant admits the allegations of Paragraph 37.

38. Paragraph 38 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with the Medicare Act and its legislative history. Defendant also states that the Medicare Act speaks for itself.

39. Paragraph 39 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with the Medicare Act and its legislative history. Defendant also states that the Medicare Act speaks for itself.

Responding to the paragraph listed as subheading “2.” in the Factual Background section, Defendant states that the paragraph sets forth a legal conclusion, which does not require a response. To the extent that a response is required, Defendant denies the allegations of the paragraph to the extent they are inconsistent with applicable rules, regulations and other laws. Finally, the allegations of the paragraph relate solely to Count II of the First Amended



Complaint. Because the parties jointly stipulated to the dismissal of Count II of the First Amended Complaint on June 27, 2007, no response to these allegations is required.

40-48. Paragraphs 40 to 48 set forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with applicable regulations, rules and other laws. Defendant also states that the rules, regulations, laws and other authorities cited in Paragraphs 40-48 speak for themselves. Finally, the allegations of Paragraphs 40-48 relate solely to Count II of the First Amended Complaint. Because the parties jointly stipulated to the dismissal of Count II of the First Amended Complaint on June 27, 2007, no response to these allegations is required.

Responding to the paragraph listed as subheading “3.” in the Factual Background section, Defendant states that the paragraph sets forth a legal conclusion, which does not require a response. To the extent that a response is required, Defendant denies the allegations of the paragraph to the extent they are inconsistent with applicable rules, regulations and other laws.

49. Paragraph 49 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with 42 U.S.C § 1320a-7b(b) and its legislative history. Defendant also states that 42 U.S.C § 1320a-7b(b) speaks for itself.

50. Defendant admits that in 1994, the Office of the Inspector General of the U.S. Department of Health and Human services issued a Special Fraud Alert regarding possible violations of the anti-kickback statute in connection with the marketing of prescription drugs. Defendant denies the allegations set forth in Paragraph 50 to the extent they are inconsistent with the referenced Special Fraud Alert. Defendant also states that the referenced Special Fraud Alert speaks for itself.

Responding to the paragraph listed as subheading “4.” in the Factual Background section, Defendant states that the paragraph sets forth a legal conclusion, which does not require a response. To the extent that a response is required, Defendant denies the allegations of the paragraph to the extent they are inconsistent with applicable rules, regulations and other laws. Finally, the allegations of the paragraph relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required.

51-52. Paragraphs 51 to 52 set forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies those allegations that are inconsistent with applicable regulations, rules and other laws. Defendant also states that the rules, regulations, laws and other authorities cited in Paragraphs 51 to 52 speak for themselves. Finally, the allegations of Paragraphs 51 to 52 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required.

Responding to the paragraph listed as subheading “5.” in the Factual Background section, Defendant states that the paragraph sets forth a legal conclusion, which does not require a response. To the extent that a response is required, Defendant denies the allegations of the paragraph to the extent they are inconsistent with applicable rules, regulations and other laws.

53. Paragraph 53 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies the allegations of the paragraph to the extent they are inconsistent with the Prescription Drug Marketing Act and its legislative history. Defendant also states that the Prescription Marketing Act speaks for itself.

Responding to the paragraph listed as subheading “B.” in the Factual Background section, Defendant admits that one of its drugs is named Procrit.

54. Defendant denies that it ever manufactured Procrit. Defendant admits that it marketed Procrit in the United States when Mark Duxbury was Defendant’s employee. Defendant is without sufficient information to admit or deny the remaining allegations in this paragraph; those allegations are therefore denied.

55. Defendant admits that Procrit is the brand name for epoetin alfa and that Procrit has been approved by the FDA for, among other things, use in treating anemia caused by chemotherapy and blood loss from certain types of surgery. Defendant denies the remaining allegations of Paragraph 55.

56. Paragraph 56 contains Relator’s characterization of Procrit’s price, to which no answer is required. To the extent an answer is required, Defendant denies the allegations of Paragraph 56.

57. Defendant is without sufficient information to admit or deny the the allegations of Paragraph 57; those allegations are therefore denied.

58. Defendant is without sufficient information to admit or deny the the allegations of Paragraph 58; those allegations are therefore denied.

59. Paragraph 59 sets forth legal conclusions, which do not require a response. In addition, the allegations of Paragraph 59 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required.

60-63. The allegations of Paragraphs 60 to 63 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required.

Responding to the paragraph listed as subheading “C.” in the Factual Background section, Defendant states that the paragraph sets forth a legal conclusion, which does not require a response. To the extent that a response is required, Defendant denies the allegations of the paragraph.

Responding to the paragraphs listed as subheadings “C(1).” and “a.” in the Factual Background section, Defendant states that those paragraphs relate solely to Count II of the First Amended Complaint. Because the parties jointly stipulated to the dismissal of Count II of the First Amended Complaint on June 27, 2007, no response to these allegations is required. To the extent that a response is required, the allegations of these paragraph are denied.

64-130. No response to the allegations in Paragraphs 64 to 130 is required because these paragraphs relate solely to Count II of the First Amended Complaint, to which the parties jointly stipulated to dismissal on June 27, 2007. Moreover, there are no allegations in these paragraphs falling within the scope of the Court’s September 27, 2010, decision narrowing the scope of Relator’s Count I to claims from (i) the eight-month period from November 6, 1997 to July 20, 1998 and (ii) St. Josephs Hospital, Tacoma, Washington; Rainier Oncology of Puyallup, Washington; Western Washington Cancer Treatment Center in Olympia, Washington; Memorial Clinic in Olympia, Washington; and Memorial Clinical Oncology Group in Washington. Finally, many of the allegations in these paragraph relate solely to Dean McClellan, and all claims by Dean McClellan were dismissed by Order of the Court dated January 28, 2008. To the extent that a response is required to any of these paragraphs 64 to 130, Defendant denies them.

131-210. The allegations of Paragraphs 131 to 210 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required. Moreover, there are no allegations in these paragraphs falling within the scope of the Court's September 27, 2010, decision narrowing the scope of Relator's Count I to claims from (i) the eight-month period from November 6, 1997 to July 20, 1998 and (ii) St. Josephs Hospital, Tacoma, Washington; Rainier Oncology of Puyallup, Washington; Western Washington Cancer Treatment Center in Olympia, Washington; Memorial Clinic in Olympia, Washington; and Memorial Clinical Oncology Group in Washington. Finally, many of the allegations in these paragraph relate solely to Dean McClellan, and all claims by Dean McClellan were dismissed by Order of the Court dated January 28, 2008. To the extent that a response is required to any of these paragraphs 131 to 210, Defendant denies them.

Responding to the paragraph listed as subheadings "D." in the Factual Background section, Defendant states that the paragraph sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant denies the allegations of the paragraph.

211. The allegations of subparts "e.", "f." and "h." of Paragraph 211 relate in their entirety to alleged false claims that occurred before November 6, 1997. Because the scope of Relator's claims were narrowed by Order of the Court dated September 27, 2010 to the eight-month period from November 6, 1997 to July 20, 1998, no response to these allegations is required. To the extent a response is required, Defendant is without sufficient information to admit or deny those allegations; those allegations are therefore denied. The allegations in subparagraphs "a.", "b.", "c.", "d." and "g." of Paragraph 211 that relate to alleged false claims that occurred before November 6, 1997, likewise do not require a response. To the extent a

response is required, Defendant is without sufficient information to admit or deny those allegations; those allegations are therefore denied. Defendant is without sufficient information to admit or deny the remaining allegations of Paragraph 211; those allegations are therefore denied.

212-217. The allegations of Paragraphs 212 to 217 relate solely to claims alleged by Dean McClellan. Because all claims alleged by Dean McClellan were dismissed by Order of the Court dated January 28, 2008, Defendant is not required to respond to these allegations. To the extent a response is required, Defendant is without sufficient information to admit or deny the allegations; those allegations are therefore denied.

218-225. The allegations of Paragraphs 218 to 225 relate to Defendant's conduct throughout the United States. No response is required because this Court's September 27, 2010, decision narrowed the scope of Relator's Count I to St. Josephs Hospital, Tacoma, Washington; Rainier Oncology of Puyallup, Washington; Western Washington Cancer Treatment Center in Olympia, Washington; Memorial Clinic in Olympia, Washington; and Memorial Clinical Oncology Group in Washington. To the extent a response is required, Defendant is without sufficient information to admit or deny the allegations; the allegations are therefore denied.

### **AS TO COUNT I**

#### **KICKBACKS IN VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(1), (a)(2), and 3732(b))**

226. Defendant repeats and realleges its responses to Paragraphs 1 through 225 of the First Amended Complaint, as if fully set forth herein.

227. Paragraph 227 contains Relator's characterization of Count I, to which no answer is required. To the extent an answer is required, Defendant admits that Relator is attempting to state a claim under the FCA, but deny that she is entitled to any relief.

228. Paragraph 228 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

229. Paragraph 229 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

230. Paragraph 230 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

231. Paragraph 231 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

232. This Court's September 27, 2010, decision narrowed the scope of Relator's Count I to claims from (i) the eight-month period from November 6, 1997 to July 20, 1998 and (ii) provider accounts about which Relator had direct and independent knowledge: St. Josephs Hospital, Tacoma, Washington; Rainier Oncology of Puyallup, Washington; Western Washington Cancer Treatment Center in Olympia, Washington; Memorial Clinic in Olympia, Washington; and Memorial Clinical Oncology Group in Washington. To the extent the allegations of Paragraph 232 address claims going beyond these restrictions, no response is required. To the extent a response is required, the allegations of this paragraph are denied.

233. Defendant is without sufficient information to admit or deny the allegations of Paragraph 233; those allegations are therefore denied.

234. Defendant is without sufficient information to admit or deny the allegations of Paragraph 234; those allegations are therefore denied.

235. Defendant is without sufficient information to admit or deny the allegations of Paragraph 235; those allegations are therefore denied.

236. Defendant is without sufficient information to admit or deny the allegations of Paragraph 236; those allegations are therefore denied.

237. Defendant is without sufficient information to admit or deny the allegations of Paragraph 237; those allegations are therefore denied.

238. Paragraph 238 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant is without sufficient information to admit or deny the allegations of Paragraph 238; those allegations are therefore denied.

239. Paragraph 239 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

240. Paragraph 240 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

241. Paragraph 241 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant is without sufficient information to admit or deny the allegations of Paragraph 241; those allegations are therefore denied.

242. Paragraph 242 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

243. Paragraph 243 sets forth legal conclusions, which do not require a response. To the extent that a response is required, Defendant is without sufficient information to admit or deny the allegations of Paragraph 243; those allegations are therefore denied.

244. Paragraph 244 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.

245. Paragraph 245 sets forth legal conclusions, which do not require a response. To the extent that a response is required, the allegations of this paragraph are denied.



246. To the extent the allegations of Paragraph 246 address claims other than those from the eight-month period from November 6, 1997 to July 20, 1998, no response is required. This Court's September 27, 2010, decision narrowed the scope of Relator's Count I to, among other things, claims from the eight-month period from November 6, 1997 to July 20, 1998. To the extent a response is required, Defendant is without sufficient information to admit or deny the allegations of Paragraph 246; those allegations are therefore denied.

247. Defendant is without sufficient information to admit or deny the allegations of Paragraph 247; those allegations are therefore denied.

### **AS TO COUNT II**

#### **SCHEME TO INCREASE THE AWP SPREAD IN VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(1), (a)(2), and 3732(b))**

248-268. The allegations of Paragraphs 248 to 268 relate solely to Count II of the First Amended Complaint. Because the parties jointly stipulated to the dismissal of Count II of the First Amended Complaint on June 27, 2007, no response to these allegations is required. To the extent that a response is required, the allegations of this paragraph are denied.

### **AS TO COUNT III**

#### **INFLATED DOSING SCHEME IN VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(1) and 3732(b))**

269-287. The allegations of Paragraphs 269 to 287 relate solely to Count III of the First Amended Complaint. Because Count III was dismissed by Order of the Court dated January 28, 2008, no response to these allegations is required. To the extent that a response is required, the allegations of this paragraph are denied.

Defendant denies any and all allegations of Relator's First Amended Complaint not expressly admitted herein.

**AFFIRMATIVE DEFENSES**

1. Relator's First Amended Complaint fails to state a claim upon which relief can be granted.
2. Relator's claims are barred because Defendant has not made, or caused to be made, any false claims.
3. Relator's claims are barred, in whole or in part, by the statute of limitations.
4. Relator's claims are barred, in whole or in part, under the doctrine of laches.
5. Relator's claims are barred, in whole or in part, under the doctrine of unclean hands.
6. Relator's claims are barred, in whole or in part, under the doctrine of release.
7. Relator's claims are barred, in whole or in part, under the doctrine of estoppel.
8. Relator's claims are barred, in whole or in part, under the doctrine of waiver.
9. Relator's claims are barred to the extent that Relator's substitution as Relator for Mark Eugene Duxbury is contrary to law and unfairly prejudicial to Defendant.
10. Relator's First Amended Complaint fails to state a claim over which this Court has jurisdiction.

WHEREFORE, Defendant respectfully requests that the Court enter judgment in its favor on all claims alleged in the First Amended Complaint; award Defendant the costs, including attorneys' fees, incurred in defending this action; and grant Defendant such other relief as this Court deems just and proper.

**JURY DEMAND**

Defendant demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Respectfully Submitted,

Date: July 1, 2011

/s/ Anne Y. Lee  
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**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the forgoing was served upon the following attorneys by Email and/or First Class Mail on July 1, 2011:

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